REMARKS

Status of the Claims

Claims 1-12 are pending. Claims 9-12 are withdrawn from examination as being directed to a separate invention. Claims 1-8 are currently under examination.

Amendments to the Claim

Claims 1-9 have been amended to delete the terms "solvate" and "pro-drug" without prejudice or disclaimer and to replace the term "pro-drug" with "*in vivo* hydrolysable ester or amide." Representative support for the phrase "*in vivo* hydrolysable ester or amide" can be found on page 8, line 16 to page 9, line 13.

Claim 8 also has been amended to insert the phrase "an effective amount." Representative support for this amendment can be found on page 10, lines 2 and 3.

The amendments to claims 1-9 do not introduce prohibited new matter.

Election/Restriction

The Office Action acknowledges that PCT Rule 13 provides that unity of invention exists for an independent claim to a product, an independent claim to a method of manufacturing the product, and an independent claim to a method of using a product. However, claim 9, directed to a first method of making the product of claim 1, has not been examined with claims 1-8, currently under examination as being directed to products. Claim 11 is dependent upon claim 9. Thus, at a minimum, both claims 9 and 11 should be examined with claims 1-8 to the extent that they read on the elected invention of Group I.

Moreover, PCT Rule 13 also provides that unity of invention exists for intermediate and final products, if they have the same essential structural elements. Claim 10 is directed to an intermediate of the products of claims 1-8. The products of claim 10 have the same essential structural element as the products of claims 1-8 (see formulae III and I). Accordingly, at a minimum, claims 10 and 12 should also be examined with claims 1-8 to the extent that they read on the elected invention of Group I.

Further, Applicant respectfully points out that MPEP 821.04(b) states that once a product claim is found allowable, withdrawn method claims which depend from or otherwise include all

the limitations of the allowable product claim must be rejoined. Thus, once a claim directed to the product is found allowable, withdrawn method claims (claims 9 and 11) which depend from or otherwise include all the limitations of the allowed claim must be rejoined.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-8 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

The Office Action alleges that claims 1-8 provide no indication as what "pro-drugs" and "solvates" really are.

Applicants respectfully point out that they do not agree with this rejection. However, in the interest of advancing the prosecution of this application to allowance, Applicants have deleted the term "solvate" from the claims and have replaced "pro-drug" with "*in vivo* hydrolysable ester or amide."

Applicants respectfully point out that the term "solvate" is redundant and its removal does not affect the scope of these claims. In particular, Applicants maintain that any person skilled in this art would clearly be aware of what a solvate is, and that this art is sufficiently developed so that such skilled persons would have no difficulty in determining what solvent components of a solvate would be acceptable within the context of the claimed compounds and compositions. Nevertheless, it is apparent that whether a chemically defined compound is or is not in the form of a solvate is immaterial to the scope of these claims, and this superfluous recitation has therefore been removed by the above amendments, thus obviating this ground for rejection.

A solvate, in the pharmaceutical context as defined in Stedman's Medical Dictionary (and similarly in the PDR Medical Dictionary), is simply "a nonaqueous solution or dispersoid in which there is a noncovalent or easily reversible combination between solvent and solute, or dispersion means and disperse phase; when water is the solvent or dispersion medium, it is called a hydrate." The solvent molecule of a solvate has been described as a species introduced into the crystal and no part of the organic host molecule is left out or replaced (see, *e.g.*, West, Solid State Chemistry at page 358). Thus, whether a chemically defined compound is or is not noncovalently associated with a solvent does not affect the scope of the claim to the compound,

per se, any more than placing such compound in solution would remove the compound from the scope of such claim. Therefore, the alternative recitation of "a solvate ... thereof" is seen as being entirely superfluous, and neither expands nor contracts the scope of these claims. In other words, a claim to a novel compound *per se* encompasses such compound, regardless of its state of solvation or hydration, or its polymorphic form, and regardless of whether it is a racemic mixture or a resolved enantiomer.

Therefore, since the alternative recitation of "a solvate ... thereof" does not, and is not intended to, expand or limit the scope of these claims, all reference to the compounds alternatively being in the form of a "solvate" has been removed from the claims in order to expedite the prosecution of this application to allowance.

Applicants respectfully point out that the term "pro-drug" is replaced with the phrase "*in vivo* hydrolysable ester or amide," which is described in detail on page 8 line 15 to page 9 line 13. The specification describes how to obtain *in vivo* hydrolysable esters or amides. Also, *in vivo* hydrolysable esters and amides are well known in the art. Further, the specification provides specific examples of *in vivo* hydrolysable ester, in particular on page 8, line 30 to page 9, line 13. Thus, the specification enables "*in vivo* hydrolysable ester or amide."

Accordingly, this rejection has been overcome by the cancelation of the terms "solvate" and "pro-drug" from all claims. This rejection is not applicable to the phrase "*in vivo* hydrolysable ester or amide" for the reasons discussed above.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 1-8 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

The Office Action alleges that the terms "solvate" and "pro-drug" render the claims indefinite. Without acquiescing to the propriety of this rejection, Applicants have canceled the terms.

As discussed above, the deletion of the term "solvate" from the claims does not change the scope of the claims, since the recitation of the term "solvate" in the claims is redundant. Also, as discussed above, the term "pro-drug" has been replaced with the phrase "*in vivo* hydrolysable ester or amide" which is described on page 8, line 15 to page 9, line 13 of the

specification and which is well known in the art. Accordingly, this rejection is not applicable to the phrase "*in vivo* hydrolysable ester or amide."

Claim 8 is also indefinite for failing to recite "an effective amount." Claim 8 has been amended to insert the phrase "an effective amount" to clarify the claimed invention.

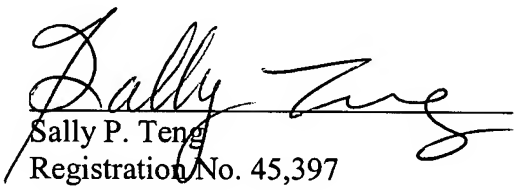
Thus, this rejection has been overcome by the amendments to the claims.

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should an interview be helpful to further prosecution of this application, the Examiner is invited to telephone the undersigned.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,
Morgan, Lewis & Bockius LLP



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